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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,003	11/21/2005	Tae Seok Moon	CMT-0007	4859
23413	7590	10/23/2007	EXAMINER	
CANTOR COLBURN, LLP			BLAND, LAYLA D	
55 GRIFFIN ROAD SOUTH				
BLOOMFIELD, CT 06002				
			ART UNIT	PAPER NUMBER
			1623	
			MAIL DATE	DELIVERY MODE
			10/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,003

Applicant(s)

MOON ET AL.

Examiner

Layla Bland

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/18/2005, 4/25/2005.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

This application is a national stage entry of International Application No. PCT/KR03/00998, filed May 21, 2003, and claims benefit of Korean Application No. 10-2002-0044261, filed July 26, 2002. Claims 1-13 are pending in this application and are examined on the merits herein.

Information Disclosure Statement

Only the English abstracts of the Japanese and Korean documents of the IDS submitted April 18, 2005 and April 25, 2005 were considered.

Claim Objections

Claim 13 objected to because of the following informalities: the claim recites "claims 1," which should be "claim 1." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 (and dependent claims) recites the limitation "derivative." Neither the claim nor the specification defines what derivatizations may be present. Thus, it is impossible to determine the metes and bounds of the claims.

Claim 8 (and dependent claims) is drawn to a method wherein a "main agent" and an "auxiliary agent" are used for activation of the carbonyl groups. It is unclear what is meant by "main agent" and "auxiliary agent" and how the two differ.

Claim 12 recites the limitation "for 0.5 hour 144 hours." It is unclear what time period is intended. For the purposes of examination, it is assumed that a range from 0.5 hour to 144 hours was intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Moon et al. (WO 02/30990, April 18, 2002).

Moon et al. teach water-insoluble crosslinked amide derivatives of hyaluronic acid and manufacturing methods thereof [see abstract]. A 1.25 mg/ml aqueous solution of sodium hyaluronate (MW \geq 2,000,000) and a 0.625 mg/ml aqueous solution of chitosan HCL were added together with stirring. EDC and NHS were slowly added to the solution, with stirring, and the reaction continued for two hours at 25°C.

Concentrations of EDC ranged from 0.2 to 1.2 mg/ml and concentrations of NHS ranged from 0.24 to 1.44 mg/ml. Water-insoluble amide derivatives of HA crosslinked with chitosan were obtained. [pages 7 and 8, Example 1] Samples obtained in this way were suspended in 0.1 N HCl to form gels [page 10, Table 3].

In the same manner as example 1, a mixed aqueous solutions of deacetylated HA and sodium hyaluronate was stirred and EDC (0.2 mg/ml) and NHS (0.24 mg/ml) were added to the solution, followed by two hours of stirring at 25°C. Water-insoluble gel was formed in 56% yield. [page 12, Example 5]

Moon et al. do not specifically state "heat-treating" of the gel, but after addition of the activating agents, which is considered to be the "reacting" step corresponding to step c in claim 1, the mixture is further stirred at 25°C, which is within the temperature range recited in claim 12. Thus, the limitations of claim 12 are met by Moon et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,903,199.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant application and the claims of U.S. Patent No. 6,903,199 are drawn to very similar methods of manufacturing crosslinked HA derivatives and the derivatives formed by the methods. The differences in the claims are that the claims of U.S. Patent No. 6,903,199 do not require gel formation and does not specify a saccharide compound. However, claim 19 of U.S. Patent No. 6,903,199 is drawn to a crosslinked product that has the form of a gel. Furthermore, the use of chitosan is exemplified in the specification of U.S. Patent No. 6,903,199. Thus, the instant claims are obvious over claims 1-19 of U.S. Patent No. 6,903,199.

Conclusion

No claims are allowed.

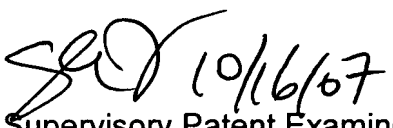
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571) 272-0627. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Layla Bland
Patent Examiner
Art Unit 1623
October 16, 2007

Shaojia Anna Jiang

Supervisory Patent Examiner
Art Unit 1623
October 16, 2007